IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	Civ. Action No. 05-356-KAJ (consolidated)

DEFENDANTS BARR LABORATORIES, INC.'S AND BARR PHARMACEUTICALS, INC.'S REDACTED OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

The ultimate question to be decided at the end of this case is whether claims 1 and 4 of the '318 patent are valid.[1] For present purposes, the Court is being asked to construe four disputed claim terms, which are found in claim 1 of the '318 patent: (1) "Alzheimer's disease and related dementias;" (2) "a method of treating;" (3) "therapeutically effective;" and (4) "patient." Barr contends that all four disputed terms are well known in the medicinal art, and should be construed to have their ordinary meaning as known to a person of ordinary skill in the art.[2] In contrast, Plaintiffs propose meanings for the disputed terms that are vague, ambiguous, and appear to redefine the scope of the invention disclosed in the '318 patent. Specifically, Plaintiffs either attempt to import a series of complex, largely commercial requirements into the patent claims that do not appear in the claim language and are not supported by the intrinsic evidence of the patent, or they rewrite the asserted claims to read out claim language that appears on the face of the patent.

Plaintiffs' efforts are a transparent attempt to redefine the claim language to avoid a wealth of invalidating prior art and a finding that Dr. Davis failed to enable the full scope of her claims. Plaintiffs' efforts should be rejected as contrary to well-settled law.

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[1] The '318 patent refers to U.S. Patent No. 4,663,318. All references to "Exhibit _" or "Ex. _" refer to the exhibits attached to the Declaration of Brian E. Farnan filed contemporaneously herewith. A copy of the '318 Patent is attached to the Farnan Declaration as Exhibit 1.

[2] As set forth in Defendants' Expert Reports, a person of ordinary skill in the art with respect to the '318 Patent as of January 15, 1986 would have been a M.D. or Ph.D. interested in the field of Alzheimer's disease research (which would include M.D. and Ph.D. students as well as doctors and researchers in the fields of pharmacology, geriatrics, psychiatry, neurology, neuroscience or pharmacy), who, as a result of such training and/or interest, would have knowledge of the cholinergic deficiency hypothesis of Alzheimer's disease, the role of acetylcholine in memory, and pharmacological strategies and approaches for treating Alzheimer's disease and related dementias (*See, e.g.*, Opening Expert Report of Dr. Allan Levey at ¶ 19, attached to Farnan Declaration as Exhibit 2). Plaintiffs have given no indication that any of their proposed constructions would be affected in any way by any disagreement with this definition.

II. BACKGROUND OF THE '318 PATENT

The application that issued as the '318 patent was filed by Dr. Bonnie Davis in January 1986. The '318 patent is directed to a method of treating Alzheimer's disease and related dementias by administering a therapeutically effective amount of galanthamine. In 1986, dementia was recognized as the hallmark symptom of Alzheimer's disease. "Dementia is a general term for many types of brain disorders that share common features of impairment of memory and other cognitive functions and that are sufficiently severe to impact on social or occupational functioning." (Ex. 2 at ¶ 68).

By the time the '318 patent application was filed in 1986, it had been discovered that Alzheimer's disease was characterized by a decrease in the levels of the neurotransmitter acetylcholine, and the deficiency of acetylcholine was in turn found to correlate with the severity of dementia. (*Id* at ¶¶ 28-29). This phenomenon came to be known as the cholinergic deficiency hypothesis. "In its simplest terms, the cholinergic deficiency hypothesis is that there is a loss of acetylcholine in the brains of Alzheimer's disease patients, and that this deficiency contributes to the symptoms of the disease." (*Id.* at ¶ 29).

Galanthamine belongs to the class of drugs known as reversible cholinesterase inhibitors. Dr. Davis did not discover galanthamine. She also did not discover that galanthamine has possible therapeutic benefits. Prior to her patent, galanthamine had been used in Eastern Europe since at least the 1950s to treat a variety of central nervous system disorders. (*Id.* at ¶¶ 25, 47).

It is undisputed that when Dr. Davis filed her patent in 1986, it was known in the art that reversible cholinesterase inhibitor drugs like galanthamine had the ability to

inhibit the degradation of acetylcholine. (*Id.* at ¶ 27). More specifically, it was known that reversible cholinesterase inhibitors improved cognitive function or functional status in patients with Alzheimer's disease. (*Id* at ¶¶ 32-36). That discovery was made by others, including Dr. Davis' husband, Dr. Kenneth Davis, in the late 1970s to early 1980s. (*Id* at ¶ 29). In particular, it was known to those of ordinary skill in the art that the reversible cholinesterase inhibitor drug physostigmine had been shown in clinical trials to improve the cognitive function/functional status of patients with Alzheimer's disease. (*Id.* at ¶ 113).

Given this historical background of the prior art, it is clear from the claims and specification of the '318 patent that Dr. Davis' alleged invention was simply the suggestion of a new use for galanthamine: *i e*, the improvement of the cognitive function/functional status of patients with Alzheimer's disease and related dementias. (Ex. 1, 1:41-42). In describing her invention, Dr. Davis explicitly stated that "it is an object of the present invention to improve the cognitive function of patients with Alzheimer's disease." (*Id*). Significantly, Dr. Davis did not claim that she had discovered a way of improving non-cognitive symptoms of Alzheimer's disease or of deferring the decline of the disease, as Plaintiffs now try to argue with their claim constructions. Moreover, Dr. Davis did not claim her invention in terms of its safety, tolerability or clinical meaningfulness. The words safety, tolerability and clinically meaningful do not appear anywhere in the '318 patent claims or specification. The absence of such words is not surprising because prior to filing her patent application

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It is with this background of the art and the '318 patent in mind that the Court should construe the claims of the '318 patent. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559 (Fed. Cir. 1992) (resting claim interpretation on "the fundamental purpose and significance" of the invention.).

III. GOVERNING LEGAL STANDARDS

Claim construction "is the judicial statement of what is and is not covered by the technical terms and other words of the claims." *Network, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001). In order to construe a patent claim, the court has traditionally given claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art. *Bell Atlantic Network Services, Inc. v. Covad Comm Group*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). Generally, there is a "heavy presumption" in favor of this claim construction. *Id.* at 1268. This presumption is overcome if the patentee has chosen to be her own lexicographer by clearly setting forth a different explicit definition "with reasonable clarity, deliberateness, and precision." *In re Paulson*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). This can occur when the specification "expressly defines terms used in the claims or when it defines terms by implication." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. *See Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Because the meaning of a claim term as understood by persons of

skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, courts should look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova*, 381 F.3d at 1116. Those sources include various forms of "intrinsic" evidence, such as the words of the claims themselves, the specification, and the prosecution history, as well as various forms of "extrinsic" evidence, including expert and inventor testimony, dictionaries, and treatises. *See id*

The Federal Circuit recently *clarified* the principles by which district courts should approach claim construction analysis, including with respect to the proper use of the various kinds of intrinsic and extrinsic evidence. *See Phillips v AWH Corp*, 415 F.3d 1303 (Fed. Cir. 2005). In *Phillips*, the court looked first to the language of the claims themselves, considering the meaning of particular claim terms, the context in which terms are used in the asserted claims, and other claims of the patent in question. *See id* at 1314-15.

Second, the court emphasized that "claims must be read in view of the specification," which the court described as "highly relevant to the claim construction analysis." *Id* at 1315. In fact, the Federal Circuit explained that the specification is "the single best guide to the meaning of a disputed term." *Id* (quoting *Vitronics Corp v Conceptronic, Inc*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). For these reasons, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Phillips*, 415 F.3d at 1317.

Third, the court stated that, in addition to consulting the specification, a district court also should consider the patent's prosecution history, if it is in evidence. *See id.* (internal quotation omitted). However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

Finally, the Federal Circuit confirmed that district courts are authorized to rely on extrinsic evidence. In particular, the court noted that dictionaries and treatises can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention, and that expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field. *Id.* at 1318. However, the Court made clear that extrinsic evidence should be disregarded where it is "clearly at odds with the claim construction mandated by the claims themselves . . . [and] the written record of the patent." *Id.* at 1318, 1320-24.

IV. CLAIM CONSTRUCTION OF DISPUTED TERMS

Only independent claim 1 presents questions of claim construction for the Court. This claim (with disputed terms underlined) provides as follows:

> 1. A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically acceptable acid addition salt thereof.

The parties have exchanged proposed claim construction positions on the various disputed terms in claim 1. A chart setting forth the parties' respective positions concerning the construction of the disputed terms is attached to the Farnan Declaration as Exhibit 3.[3]

A. "Alzheimer's Disease and Related Dementias"

The phrase "Alzheimer's disease and related dementias" appears in claim 1 of the '318 patent. Barr contends that the term "Alzheimer's disease" as used in the '318 patent means *only* "presenile dementia" because that is how the term is explicitly defined in the patent specification: "Alzheimer's disease, presenile dementia." (Ex. 1, 1:34). Based on Plaintiffs' claim construction chart and the testimony of Plaintiffs' experts, the parties appear to agree on this meaning of the term "Alzheimer's disease."

The parties disagree, however, on the meaning of the phrase "and related dementias." Applying the governing rules of claim construction, it is Barr's position that the phrase "and related dementias" should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art as of 1986. That is, the phrase means what it says – dementias (plural) related to Alzheimer's disease. Plaintiffs, on the other hand, urge the Court to ignore the plain language of the claim and rewrite the claim to narrow it so that it effectively reads "senile dementia of the Alzheimer's type." Plaintiffs' claim construction runs contrary to established claim construction principles.

The law is clear that the plain and ordinary meaning of the term "and related dementias" should apply unless the inventor provided a special definition of the term with "reasonable clarity, deliberateness, and precision." *In re Paulson*, 30 F.3d at 1480.

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[3] This chart is a copy of the parties' Joint Claim Construction Chart (filed with this Court on December 4, 2006), which includes each party's proposed constructions and intrinsic evidence citations

Plaintiffs cannot identify anywhere in the patent claim itself, patent specification, or prosecution history where Dr. Davis deliberately and with precision limited the term "and related dementias" to senile dementia of the Alzheimer's type. If Dr. Davis had intended to so narrow her claim, she easily could have done so in very clear terms. She did not. Rather, it is evident from the claim language and the remaining intrinsic evidence that Dr. Davis intended to cover much more than senile dementia of the Alzheimer's type by the use of the plural form of dementia. Plaintiffs' construction to include only senile dementia converts the claim from the plural to the singular and simply cannot be supported by the syntax of the claim, unless the claim language is ignored. *See Biacore v. Thermo Bioanalysis Corp*, 79 F. Supp. 2d 422, 455 (D.Del. 1999) (*citing Eastman Kodak Co v. Goodyear Tire & Rubber Co*, 114 F.3d 1547, 1553 (Fed. Cir. 1997) (noting that "in analyzing claim language, the court must employ 'normal rules of syntax'")); *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983)(noting that "[a] claim must be read in accordance with the precepts of English grammar.").

Unlike Plaintiffs' construction, Barr's construction of "and related dementias" to include *more* than senile dementia comports with the intrinsic evidence of the patent. Not only is the claim language written in the plural with respect to dementias, the phrase also appears in the patent specification and prosecution history in the plural, not singular, form. Moreover, nowhere in the prosecution history does the inventor use the terminology senile dementia of the Alzheimer's type.

Barr's proposed construction of "related dementias" also comports with the extrinsic evidence. Resort to extrinsic evidence, such as expert testimony, is allowed to establish that a particular term in the patent or the prior art has a particular meaning in the

pertinent field. *See Phillips*, 415 F.3d at 1318.

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For all of these reasons, the term "and related dementias" should be given its plain and ordinary meaning as including dementias that were recognized in the art as of 1986 as being related to Alzheimer's disease.

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B. "Method of Treating"

The phrase "method of treating" is used in the preamble to claim 1. To the extent the term is a limitation at all, the term should be given its plain and ordinary meaning to a person of ordinary skill in the art. *See Pitney Bowes, Inc v Hewlett-Packard Co*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (noting that where "the body of the claim fully and intrinsically sets forth the complete invention . . . then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."). The ordinary meaning of a claim term is "its meaning to the ordinary artisan after reading the entire patent." *Phillips*, 415 F 3d at 1321.

The term "treating" is a well-known term used in therapeutics. Generally speaking, it is used to describe "any specific procedure used for the cure or the amelioration of a disease or pathological condition." (Taber's Cyclopedic Medical Dictionary, 18th ed., p. 1990 (2005) (online version available at http://www.rxlist.com/cgi/tabersearch2.cgi?keyword=treatment, attached to Farnan Declaration as Exhibit 6)). For purposes of claim 1 of the '318 patent, the specification is clear that the term "treating" is used to mean the act of giving galanthamine for the purpose of trying to improve the cognitive function or functional status in patients with Alzheimer's disease and related dementias.

The patent specification states:

- At present, there is *no effective means of improving the functional status of persons with the disease.* It is an object of the present invention *to improve the cognitive function of patients* with Alzheimer's disease. (Ex. 1, 1:38-42 (emphasis added)).

- A method for treating Alzheimer's disease and related dementias which comprises administering to mammals, including humans, an

> effective Alzheimer's disease *cognitively-enhancing* amount of galanthamine . . . (*Id.* at 1:45-48 (emphasis added)).

The specification "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While resort to the prosecution history is unnecessary to construe "treating" given the clear directive of the specification, the prosecution history nevertheless comports with the above construction of "treating" as being the act of giving galanthamine to improve the cognitive/functional symptoms of Alzheimer's disease and related dementias. *See Phillips*, 415 F.3d at 1317 (noting that the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes" than the claims and the specification). Specifically, in the prosecution history, the inventor argues around the prior art raised by the patent office in particular by claiming that a certain compound, pentylenetetrazol, will not treat Alzheimer's disease because it does not "improve cognitive function in Alzheimer's patients" and therefore it is not of "use in Alzheimer's disease." ('318 File History, Amendment Responsive to Office Action of April 10, 1986 at 6 (JAN RAZ-0000036), attached to Farnan Declaration as Exhibit 7).

Significantly, Plaintiffs appear to agree with Defendants that the term "method of treating" means the act of giving galanthamine to improve the cognitive symptoms or functional status of patients with Alzheimer's disease and related dementias. However, Plaintiffs seem to want the Court to go further and read the term "treating" to include "alleviating *the symptoms* or *deferring the decline* associated with Alzheimer's disease, . . . in a manner beneficial to the patient – that is a manner that is safe, tolerable and

produces clinically meaningful results." (emphasis added). Plaintiffs' construction is not supported by the intrinsic evidence and, in fact, runs contrary to it.

First, Plaintiffs have been hopelessly vague as to what they mean by "alleviating *the symptoms* . . . associated with Alzheimer's disease." Because Plaintiffs refuse to adopt Barr's construction of "method of treating," Plaintiffs appear to argue that "treating" means the amelioration of symptoms beyond cognitive or functional, such as behavioral symptoms. If that is the case, such a reading of "treating" is not supported by the patent specification. Neither the claims nor the specification explicitly references symptoms other than cognitive and functional.

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Accordingly, the claim cannot be construed to cover such symptoms because Dr. Davis clearly was not in possession of such an invention.

Plaintiffs also have been vague about what they mean by "deferring the decline associated with Alzheimer's disease." To the extent that Plaintiffs construe "treating" as deferring the progression of the disease state, there is absolutely no indication in the patent or the prosecution history that Dr. Davis intended the phrase to have that meaning. It is undisputed that nowhere in the patent is the concept of deferring the progression of Alzheimer's disease or related dementias discussed. Again, to define method of treating as including deferring the decline associated with Alzheimer's disease would give Dr.

Davis credit for an invention that she did not possess when she filed her patent application.

Finally, neither the patent nor the prosecution history support Plaintiffs' contention that the term "treating" means that the improvement in symptoms must be accomplished in a "manner beneficial to the patient," which Plaintiffs define as requiring the treatment to be safe, tolerable and produce clinically meaningful results. At the outset, it is unclear what Plaintiffs mean by safe, tolerable and clinically meaningful results. To the extent Plaintiffs intend to construe the claim so as to import FDA-requirements pertaining to toxicity, side-effects and clinical results, such a reading is wholly unsupported by the patent and intrinsic evidence. *See Novo Nordisk A S. v Eli Lilly and Co* , No. 98-643, 1999 U.S. Dist. LEXIS 18690, at 50 (D. Del. Nov. 18, 1999) (noting that "drugs not approved by the FDA are still patentable."); *Application of Watson*, 517 F.2d 465, 476 (C.C.P.A. 1975)(noting that "the standards established by statute for the advertisement, use, sale or distribution of drugs are quite different than the requirements under the Patent Act for the issuance of a patent."). The patent does not contain any toxicity data or side-effect data on the use of galanthamine for Alzheimer's disease and related dementias. Moreover, the patent does not contain any information about the clinical results for galanthamine for Alzheimer's disease and related dementias. In short, Plaintiffs' proposed construction is vague and ambiguous at best. By accepting Plaintiffs' construction, this Court would be defining a term ("treating") which has a clear, ordinary meaning, by reference to terms which are inherently ambiguous.

Tellingly, Dr. Davis, when describing her invention, said that it was an object of her invention to "improve the cognitive function of patients with Alzheimer's disease."

(Ex. 1, 1:41-42). She did not add the limitation "in a manner beneficial to the patient" that Plaintiffs now want to add to the claims. Additionally, the words safety, tolerability and clinically meaningful results are nowhere in the language of claim 1, or the patent specification. If Dr. Davis intended for her invention to cover *only* administrations of galanthamine for Alzheimer's disease and related dementias that were safe, tolerable and produced clinically meaningful results, she could have done so. She did not.

It also is worth noting that pharmaceutical patents that claim methods of treating that are safe do so directly and expressly. They routinely include claims such as a method of treating comprising "a safe and therapeutically effective amount . . ." (*See, e g*, U.S. Patents Nos. 4,430,325 at Claim 1, 5,407,688 at Claim 1, and 7,109,201 at Claim 8, attached to Farnan Declaration as Exhibits 9, 10, and 11 respectively). The undisputed fact is that Dr. Davis did not limit her invention to treatments that were FDA-approved or only treatments that would meet FDA standards for commercial drugs. Claim 1 is not so limited by the patent.

In short, Plaintiffs' claim that the phrase "method of treating," by its very definition, includes only treatments that are safe, tolerable and "produce clinically meaningful results" is a transparent attempt to avoid the prior art, and should be disregarded by this Court.[4]

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[4] As Plaintiffs are well-aware, prior to 1986, numerous studies had been conducted (including some by Dr. Davis and her husband) using other reversible cholinesterase inhibitors to treat patients with Alzheimer's disease. The prosecution history itself recognizes this fact, noting that "useful results have been reported in some cases by treatment with physostigmine." (Ex. 7 at 2 (JAN RAZ-0000032)). It goes on to note that physostigmine "was reported to be effective in treating Alzheimer's disease." (*Id.* at 9 (JAN RAZ-0000039)). Plaintiffs' construction is clearly designed to avoid prior art which demonstrated quite clearly that other reversible cholinesterase inhibitors had been shown to improve the condition of patients suffering from Alzheimer's disease

C. "Therapeutically effective amount"

The phrase "therapeutically effective" appears in claim 1 to modify the word "amount." It is Barr's position that the term "therapeutically effective amount" should be given its plain and ordinary meaning as used in the '318 patent. That is, the phrase should be construed to mean an amount sufficient to produce the desired therapeutic change or effect – i.e., improve cognitive function/functional status - in a patient with Alzheimer's disease and related dementias. For all the reasons set forth above concerning the term "treating," Barr's construction of therapeutically-effective amount is supported by the patent and prosecution history. (*See supra* Section IV.B.).

According to Plaintiffs' construction of "therapeutically effective amount," the amount has to be "sufficient to cause a beneficial effect on symptoms of Alzheimer's disease and related dementias." Plaintiffs have not provided any explanation for what they mean by "beneficial effect." The term is vague and ambiguous, just as it was in the definition of "treating." To the extent that Plaintiffs contend that the amount has to be safe, effective and produce clinically meaningful results according to FDA standards, Barr disagrees for all of the reasons set forth above in the discussion of "treating." The Court, therefore, should adopt Barr's construction of the phrase "therapeutically effective amount."

D. "Patient"

The term "patient" appears in the language of claim 1 of the '318 patent. It is Barr's contention that the term should be construed to have its ordinary meaning as evidenced by the intrinsic evidence. In the case of the '318 patent, the inventor defined "patient" to mean "a mammal, including a human." (Ex. 1, 1:45-47) Plaintiffs contend

that the term "patient," as it is used in the '318 patent, is limited to include *only* a human. Barr's construction -- "a mammal, *including* a human" -- however, is the way the term is defined in the patent specification, if not expressly, then by implication, *see Vitronics Corp.*, 90 F.3d at 1582, and should be adopted by this Court.

> The 'Summary of the Invention' describes the invention as:
>
> A method for treating Alzheimer's disease and related dementias which comprises administering to *mammals, including humans*, an effective Alzheimer's disease cognitively-enhancing amount of galanthamine...

(Ex. 1, 1:45-49 (emphasis added)).[5] Barr's proposed construction, therefore, is consistent with and supported by the patent specification to such a degree that the specification, in fact, implicitly defines the term "patient" to mean "a mammal, including a human."[6] Indeed, viewing the language of the specification side-by-side with the language of the claim makes this point clear:

Claim	A method of treating Alzheimer's disease and related dementias which comprises administering **to a patient**...galanthamine...
Specification	A method for treating Alzheimer's disease and related dementias which comprises administering **to mammals, including humans,** ...galanthamine...

Furthermore, Barr's proposed construction follows the instruction of the Code of Federal Regulations, which states that:

> A brief summary of the invention indicating its nature and substance, which may include a statement of the object of the invention, should precede the detailed description. Such summary should, when set forth, *be*

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[5] The role of the 'Summary of the Invention' section for claim construction purposes should not be understated. Statements made in this section "are not limited to describing a preferred embodiment, but more broadly *describe the overall invention* of the [patent]." *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1348 (Fed. Cir. 2004).

[6] In addition to the reasons already cited, it is worth noting that the patent discusses "persons" with the disease *as well as* "patients" the disease. (Ex. 1, 1:38-42). This distinction would be unnecessary if "patient" took on the meaning advanced by Plaintiffs.

> *commensurate with the invention as claimed and any object recited should be that of the invention as claimed.*

37 CFR § 1.73 (2006) (emphasis added). Barr's construction of the term "patient" allows the claims of the patent to reasonably be read in such a way as to be "commensurate" with the 'Summary of the Invention.'

Finally, the prosecution history provides additional support for Barr's proposed construction. Specifically, in responding to the PTO's rejection of the '318 patent claims for indefiniteness, Bonnie Davis noted:

> Applicant currently has experiments underway using animal models which are expected to show that treatment with galanthamine *does result* in an improvement in the condition of *those* suffering from Alzheimer's disease.

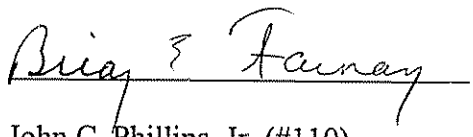
(Ex. 7 at 2 (emphasis added)). The experiments referenced in the prosecution history were conducted in mice, not in humans. Therefore, when Bonnie Davis states that the experiments "are expected to show that treatment with galanthamine *does result* in an improvement in the condition of *those* suffering from Alzheimer's disease," she must be referring to mice, as such tests in animals could not (and cannot) show that "treatment with galanthamine *does result* in an improvement in the condition" of humans. Therefore, Barr's construction should be adopted by this Court.

V. CONCLUSION

For the foregoing reasons, Barr respectfully requests that this Court adopt all of Barr's proposed claim constructions and reject Plaintiffs' proposed claim constructions.

Dated: December 11, 2006

Respectfully submitted,



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